K014215

Tab J

Premarket Notification Summary

1. **Applicant Name, Address:** W.L. Gore & Associates, Inc.
3450 W. Kiltie Lane
P.O. Box 500
Flagstaff, AZ 86002-0500

Contact Person: Jacqueline Kalbach
(928)864-3731

Date of Summary: December 20, 2001

2. **Classification Name:** Biliary catheter

Common or Usual Name: Biliary stent

Trade or Proprietary Name: VIABIL™ Biliary Endoprosthesis

3. **Device Predicates:** Microvasive Modified Biliary Wallstent®, Wallstent® Biliary Transhepatic Endoprosthesis with Unistep™ Plus Delivery System, Cordis S.M.A.R.T.™ Nitinol Stent Transhepatic Biliary System, Cordis S.M.A.R.T.™ Nitinol Stent Endoscopic Biliary System, Wilson-Cook ST-2 Soehendra Tannenbaum® Biliary Stent

4. **Device Description:** The VIABIL Biliary Endoprosthesis is a flexible, self-expanding stent-graft that is radially compressed and secured onto the distal end of a delivery catheter. The catheter provides a means for implanting the VIABIL Biliary Endoprosthesis at the target site in the biliary tract. There are two principle components of the device: the Biliary Endoprosthesis and the Delivery Catheter. Two catheter lengths are available: a 75 cm working length catheter for percutaneous delivery of the endoprosthesis, and a 195 cm working length catheter for endoscopic delivery. The endoprosthesis is available in two diameters (8 mm and 10 mm), and four nominal lengths (4 cm, 6 cm, 8 cm, and 10 cm).

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5. **Intended Use**: The VIABIL Biliary Endoprosthesis is indicated for the treatment of malignant biliary strictures.

6. **Technological Characteristics**: Similar to the Microvasive Modified Biliary Wallstent® (i.e., a covered stent), the VIABIL Biliary Endoprosthesis is a stent-graft. The stent is made of nitinol, the same material used in the Cordis S.M.A.R.T.™ Nitinol Stent Transhepatic Biliary System and Cordis S.M.A.R.T.™ Nitinol Stent Endoscopic Biliary System devices.

7. **Assessment of Performance Data**: Preclinical *in vitro* testing, preclinical *in vivo* testing, and clinical testing have demonstrated that the VIABIL Biliary Endoprosthesis is substantially equivalent to its predicate device.

8. **Conclusion**: Preclinical *in vitro* testing has demonstrated the reliability of the VIABIL Biliary Endoprosthesis and its delivery catheter. Preclinical *in vivo* testing has cofirmed the safety and efficacy of the VIABIL Biliary Endoprosthesis in terms of delivery and deployment, functionality, and biological response. The results of the clinical study with the VIABIL Biliary Endoprosthesis demonstrated the safety and effectiveness of the device for endoscopic and percutaneous approaches. The comparison to the historical control demonstrated the substantial equivalence of the VIABIL Biliary Endoprosthesis to its predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 1 9 2002

Ms. Jacqueline Kalbach
Regulatory Affairs Associate
W.L. Gore and Associates, Inc.
3450 West Kiltie Lane
FLAGSTAFF AZ 86001

Re: K014215
Trade/Device Name: VIABIL™ Biliary Endoprosthesis
Regulation Number: 21 CFR §876.5010
Regulation Name: Biliary catheter and accessories
Regulatory Class: II
Product Code: 78 FGE
Dated: September 26, 2002
Received: September 27, 2002

Dear Ms. Kalbach:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act and the limitations described below. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

The Office of Device Evaluation has determined that there is a reasonable likelihood that this device will be used for an intended use not identified in the proposed labeling and that such use could cause harm. Therefore, in accordance with Section 513(i)(1)(E) of the Act, the following limitation must appear in the Warnings section of the device's labeling:

> The safety and effectiveness of this device for use in the vascular system have not been established.

Furthermore, the indication for biliary use must be prominently displayed in all labeling, including pouch, box, and carton labels, instructions for use, and other promotional materials, in close proximity to the trade name, of a similar point size, and in bold print.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and permits your device to proceed to the market. This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification if the limitation statement above is added to your labeling, as described.

Please note that the above labeling limitations are required by Section 513(i)(1)(E) of the Act. Therefore, a new 510(k) is required before these limitations are modified in any way or removed from the device's labeling.

If you desire specific information about the application of other labeling requirements to your device (21 CFR Part 801 and additionally Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4616. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification"(21 CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html.

Sincerely yours,

Daniel G. Schultz, M.D.
Director
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number (if known): K014215

Device Name: VIABIL™ Biliary Endoprosthesis

FDA's Statement of the Indications for Use for device:

The VIABIL™ Biliary Endoprosthesis is indicated for the treatment of malignant biliary strictures.

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K014215